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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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<b>Application Number</b>	10/075,924
<b>Filing Date</b>	February 12, 2002
<b>First Named Inventor</b>	Rebecca REDMAN
Group Art Unit	1646
Examiner Name	
Attorney Docket Number	INBI-009/01US

## **U.S. PATENT DOCUMENTS**

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Signature**

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Date  
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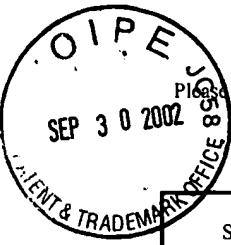
Substitute for form 1449A/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	10/075,924
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				First Named Inventor	Rebecca REDMAN
				Group Art Unit	1646
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
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✓	D1	ABELE-HORN, M. et al., "Decrease In Nosocomial Pneumonia In Ventilated Patients By Selective Oropharyngeal Decontamination (SOD)," <i>Intensive Care Med</i> 1997;23:187-95.			T
✓	D2	AERDTS, S. et al., "Prevention Of Bacterial Colonization Of The Respiratory Tract And Stomach Of Mechanically Ventilated Patients By A Novel Regimen Of Selective Decontamination In Combination With Initial Systemic Cefotaxime," <i>J Antimicrob Chemotherapy</i> 1990;26:59-76.			
✓	D3	AERDTS, S. et al., "Antibiotic Prophylaxis Of Respiratory Tract Infection In Mechanically Ventilated Patients," <i>Chest</i> 1991;100:783-91.			
✓	D4	AERDTS, S. et al., "Prophylaxis Of Infection By Selective Decontamination In Mechanically Ventilated Patients," <i>Drugs</i> 1988;35:97-9.			
✓	D5	ARMSTRONG, P. et al., "Epidemiology Of <i>Pseudomonas aeruginosa</i> In An Intensive Care Unit Using Selective Decontamination Of The Digestive Tract," <i>J Hosp Infect</i> 1992;20:199-208.			
✓	D6	ARNOW, P. et al., "Randomized Controlled Trial Of Selective Bowel Decontamination For Prevention Of Infections Following Liver Transplantation" <i>Clin Infect Dis</i> 1996;22:997-1003.			
✓	D7	"ASHP Therapeutic Guidelines for Nonsurgical Antimicrobial Prophylaxis. American Society of Health-System Pharmacists," <i>Am J Health Syst Pharm</i> 1999;56:1201-50.			
✓	D8	BERGMANS, D. et al., "Prevention Of Ventilator-Associated Pneumonia By Oral Decontamination," <i>Am J Resp Crit Care Med</i> Vol. 164, pp. 382-388, 2001			
✓	D9	BION, J. et al., "Selective Decontamination Of The Digestive Tract Reduces Gram-Negative Pulmonary Colonization But Not Systemic Endotoxemia In Patients Undergoing Elective Liver Transplantation," <i>Crit Care Med</i> 1994;22:40-49.			
✓	D10	BLAIR, P. et al., "Selective Decontamination Of The Digestive Tract: A Stratified, Randomized, Prospective Study In A Mixed Intensive Care Unit," <i>Surgery</i> 1991;110:303-309.			
✓	D11	BONTEN, M. et al., "Colonization in Patients Receiving and Not Receiving Topical Antimicrobial Prophylaxis," <i>American Journal of Respiratory and Critical Care Medicine</i> , 1994; 150:1332-1340			
✓	D12	BRUN-BUISSON, C. et al., "Intestinal Decontamination For Control Of Nosocomial Multiresistant Gram-Negative Bacilli," <i>Annals of Intern Med</i> 1989;110:873-81.			
✓	D13	CERRA, F. et al., "Selective Gut Decontamination Reduces Nosocomial Infections And Length Of Stay But Not Mortality Or Organ Failure In Surgical Intensive Care Unit Patients," <i>Arch Surg</i> 1992;127:163-167.			
✓	D14	COCKERILL, F. et al., "Prevention Of Infection In Critically Ill Patients By Selective Decontamination Of The Digestive Tract," <i>Annals of Intern Med</i> 1992;117:545-553.			
✓	D15	COOK, D. et al., "Rules Of Evidence And Clinical Recommendations On The Use Of Antithrombotic Agents," <i>Chest</i> 1992;102:305S-311S.			
✓	D16	D'AMICO, R. et al., "Effectiveness Of Antibiotic Prophylaxis In Critically Ill Adult Patients: Systematic Review Of Randomised Controlled Trials," <i>BMJ</i> 1998;316:1275-85.			
✓	D17	DERISO, A. et al., "Chlorhexidine Gluconate 0.12% Oral Rinse Reduces The Incidence Of Total Nosocomial Respiratory Infection And Nonprophylactic Systemic Antibiotic Use In Patients Undergoing Heart Surgery," <i>Chest</i> 1996;109:1556-1561.			
✓	D18	FERRER, M. et al., "Utility Of Selective Digestive Decontamination In Mechanically Ventilated Patients," <i>Annals of Intern Med</i> 1994;120:389-395.			

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Sheet	3	of	5	Attorney Docket Number	IINBI-009/01US
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✓	D19	FLAHERTY, J. et al., "Pilot Trial Of Selective Decontamination For Prevention Of Bacterial Infection In An Intensive Care Unit," <i>J Infect Dis</i> 1990;162:1393-1397.			
✓	D20	FLEISS, J., "The Statistical Basis Of Meta-Analysis," <i>Statistical Methods in Medical Research</i> 1993;2:121-146.			
✓	D21	GARCIA, M. et al., "Effectiveness And Cost Of Selective Decontamination Of The Digestive Tract In Critically Ill Intubated Patients," <i>Am J Respir Crit Care Med</i> 1998;158:908-916.			
✓	D22	GASTINNE, H. et al., "A Controlled Trial In Intensive Care Units Of Selective Decontamination Of The Digestive Tract With Nonabsorbable Antibiotics," <i>N Engl J Med</i> 1992;326:594-599.			
✓	D23	GEORGES, B. et al., "Décontamination Digestive Selective Resultats D'une Etude Chez Le Polytraumatisé," <i>Réanimation Urgences</i> 1994;3:621-627.			
✓	D24	GODARD, J. et al., "Intestinal Decontamination In A Polyvalent ICU," <i>Intensive Care Med</i> 1990;16:307-311.			
✓	D25	HAMMOND, J. et al., "Double-Blind Study Of Selective Decontamination Of The Digestive Tract In Intensive Care," <i>Lancet</i> 1992;340:5-9.			
✓	D26	HAMMOND, J. et al., "Selective Decontamination Of The Digestive Tract In Multiple Trauma Patients—Is There A Role? Results Of A Prospective, Double-Blind, Randomized Trial," <i>Crit Care Med</i> 1994;22:33-39.			
✓	D27	HAMMOND, J. et al., "Is There A Role For Selective Decontamination Of The Digestive Tract In Primarily Infected Patients In The ICU?," <i>Anaesth Intensive Care</i> 1995;23:168-174.			
✓	D28	HAMMOND, J. et al., "Neurologic Disease Requiring Long-Term Ventilation. The Role Of Selective Decontamination Of The Digestive Tract In Preventing Nosocomial Infection," <i>Chest</i> 1993;104:547-551.			
✓	D29	HARTENAUER, U. et al., "Infection Surveillance And Selective Decontamination Of The Digestive Tract (SDD) In Critically Ill Patients—Results Of A Controlled Study," <i>Infection</i> 1990;18:S22-30.			
✓	D30	HEYLAND, D. et al., "Selective Decontamination Of The Digestive Tract," <i>Chest</i> 1994;105:1221-9.			
✓	D31	HURLEY, J., "Prophylaxis With Enteral Antibiotics In Ventilated Patients: Selective Decontamination Or Selective Cross-Infection?" <i>Antimicrob Agents Chemotherapy</i> 1995;39:941-7.			
✓	D32	JACOBS, S. et al., "Effectiveness Of Selective Decontamination Of The Digestive Tract (SDD) In An ICU With A Policy Of Encouraging A Low Gastric pH," <i>Clin Intensive Care</i> 1992;3:52-58.			
✓	D33	JADAD, A. et al., "Assessing The Quality Of Reports Of Randomized Clinical Trials: Is Blinding Necessary?" <i>Controlled Clinical Trials</i> 1996;17:1-12.			
✓	D34	KERVER, A. et al., "Prevention Of Colonization And Infection In Critically Ill Patients: A Prospective Randomized Study," <i>Crit Care Med</i> 1988;16:1087-1093.			
✓	D35	KOLLEF, M. "The Role Of Selective Digestive Tract Decontamination On Mortality And Respiratory Tract Infections," <i>Chest</i> 1994;105:1101-1108.			
✓	D36	KOLLEF, M. "The Prevention of Ventilator-Associated Pneumonia," <i>NEJM</i> 1999; 340:627-634; 341:293-294			
✓	D37	KOLLEF, M. et al., "A Randomized Clinical Trial of Continuous Aspiration of Subglottic Secretions in Cardiac Surgery Patients," <i>Chest</i> 1999;116:1339-1346			
✓	D38	KORINEK, A. et al., "Selective Decontamination Of The Digestive Tract In Neurosurgical Intensive Care Unit Patients: A Double-Blind, Randomized, Placebo-Controlled Study," <i>Crit Care Med</i> 1993;21:1466-1473.			

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Sheet	4	of	5	Attorney Docket Number	INBI-009/01US

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<i>Rebecca</i>	D39	LAGGNER, A. et al., "Oropharyngeal Decontamination With Gentamicin For Long-Term Ventilated Patients On Stress Ulcer Prophylaxis With Sucralfate?" <i>Wein Klin Wochenschr</i> 1994;106:15-19			T
<i>Rebecca</i>	D40	LANGLOIS-KARAGA, A. et al., "Selective Digestive Decontamination In Multiple Trauma Patients: Cost And Efficacy," <i>Pharm World Sci</i> 1995;17:12-6.			
<i>Rebecca</i>	D41	LEDINGHAM, I. et al., "Triple Regimen of Selective Decontamination of the Digestive Tract, Systemic Cefotaxime, and Microbiological Surveillance for Prevention of Acquired Infection in Intensive Care," <i>Lancet</i> , April 9,1988; 785-790			
<i>Rebecca</i>	D42	LIBERATI, A. et al., "Antibiotics for Preventing Respiratory Tract Infections in Adults Receiving Intensive Care," (Cochrane Review), In: <i>Cochrane Library</i> , Issue 3, 2000 Oxford: Update Software			
<i>Rebecca</i>	D43	LINGNAU, W. et al., "Changing Bacterial Ecology During A Five Year Period Of Selective Intestinal Decontamination," <i>J Hosp Infect</i> 1998; 39:195-206			
<i>Rebecca</i>	D44	LINGNAU, W. et al., "Selective Intestinal Decontamination In Multiple Trauma Patients: Prospective, Controlled Trial," <i>J Trauma</i> 1997;42:687-694			
<i>Rebecca</i>	D45	LIPMAN, J. et al., "Unique Trial Design Shows SDD To Decrease And Alter Colonization Of Upper Respiratory Tract In A Multidisciplinary ICU," <i>Crit Care Med</i> 1994;144			
<i>Rebecca</i>	D46	LUITEN, E. et al., "Controlled Clinical Trial Of Selective Decontamination For The Treatment Of Severe Acute Pancreatitis," <i>Annals of Surgery</i> 1995;222:57-65			
<i>Rebecca</i>	D47	McCLELLAND, P. et al., "Reducing Sepsis in Severe Combined Acute Renal and Respiratory Failure by Selective Decontamination of the Digestive Tract," <i>Crit Care Med</i> , 1990;18:935-939			
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<i>Rebecca</i>	D51	MISSET, B. et al., "Mechanisms of Failure to Decontaminate the Gut with Polymixin E, Gentamicin and Amphotericin B in Patients in Intensive Care," <i>Eur. J. Clin. Microbiol. Infect. Dis.</i> , 1994; 13:165-170			
<i>Rebecca</i>	D52	MORAR, P. et al., "Topical Antibiotics on Tracheostoma Prevents Exogenous Colonization and Infection of Lower Airways in Children," <i>Chest</i> 2000; 117:513-518			
<i>Rebecca</i>	D53	NARDI, G. et al., "Epidemiological Impact of Prolonged Systematic Use of Topical SDD on Bacterial Colonization of the Tracheobronchial Tree and Antibiotic Resistance," <i>Internal Care Med</i> 1993;19:273-278			
<i>Rebecca</i>	D54	NATHENS, A. et al., "Selective Decontamination Of The Digestive Tract In Surgical Patients: A Systematic Review Of The Evidence," <i>Arch Surg</i> 1999;134:170-6			
<i>Rebecca</i>	D55	PALOMAR, M. et al., "Prevention Of Nosocomial Infection In Mechanically Ventilated Patients: Selective Digestive Decontamination Versus Sucralfate," <i>Clin Intensive Care</i> 1997;8:228-235			
<i>Rebecca</i>	D56	PITTET, D., "Prevention of Ventilator-associated Pneumonia by Oral Decontamination," <i>Am J Resp Crit Care Med</i> , 2000; 164:338-339			
<i>Rebecca</i>	D57	POTGIETER, P. et al., "Prophylactic Use of the New Quinolones for Prevention of Nosocomial Infection in the Intensive Care Unit," <i>Drugs</i> , 1995; 49 (Suppl.2):86-91			

Examiner Signature	<i>Rebecca</i>	Date Considered	<i>8/11/02</i>
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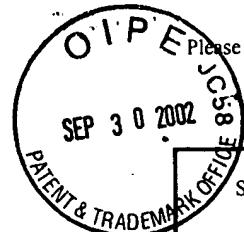
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✓	D58	PUGIN, J. et al., "Oropharyngeal Decontamination Decreases Incidence Of Ventilator-Associated Pneumonia. A Randomized, Placebo-Controlled, Double-Blind Clinical Trial," <i>JAMA</i> 1991;265:2704-2710			
	D59	QUINIO, B. et al., "Selective Decontamination Of The Digestive Tract In Multiple Trauma Patients. A Prospective Double-Blind, Randomized, Placebo-Controlled Study," <i>Chest</i> 1996;109:765-72			
	D60	ROCHA, L. et al., "Prevention Of Nosocomial Infection In Critically Ill Patients By Selective Decontamination Of The Digestive Tract," <i>Intensive Care Med</i> 1992;18:398-404			
	D61	RODRIGUEZ-ROLDAN, J. et al., "Prevention Of Nosocomial Lung Infection In Ventilated Patients: Use Of An Antimicrobial Pharyngeal Nonabsorbable Paste," <i>Crit Care Med</i> 1990;18:1239-42			
	D62	ROLANDO, N. et al., "Prospective Controlled Trial Of Selective Parenteral And Enteral Antimicrobial Regimen In Fulminant Liver Failure," <i>Hepatology</i> 1993;17:196-201.			
	D63	RUZA, F. et al., "Prevention Of Nosocomial Infection In A Pediatric Intensive Care Unit (PICU) Through The Use Of Selective Digestive Decontamination," <i>Eur J. Epidemiol</i> 1998;14:719-27.			
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	D65	SAUNDERS, G. et al., "Microbiological Surveillance During Selective Decontamination Of The Digestive Tract (SDD)," <i>J. Antimicrobial Chemo.</i> 1994; 34:529-44.			
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	D67	SILVESTRI, L. et al., "Selective Decontamination Of The Digestive Tract: A Life Saver," <i>J Hosp Infect</i> 2000;45:185-90.			
	D68	SMITH, S. et al., "Selective Decontamination In Pediatric Liver Transplants. A Randomized Prospective Study," <i>Transplantation</i> 1993;55:1306-9.			
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	D70	STOUTENBEEK, C. et al., "The Effect Of Selective Decontamination Of The Digestive Tract On Colonisation And Infection Rate In Multiple Trauma Patients," <i>Intensive Care Med</i> 1984;10:185-92.			
	D71	STOUTENBEEK, C. et al., "The Prevention Of Superinfection In Multiple Trauma Patients," <i>J Antimicrob Chemo.</i> (1984) 14, Suppl. B pp. 203=211			
	D72	STOUTENBEEK, C. et al., "Prevention Of Pneumonia By Selective Decontamination Of The Digestive Tract (SDD)," <i>Intensive Care Medicine</i> , 18: 518-523, 1992			
	D73	STOUTENBEEK, C. et al., "The Effect Of Oropharyngeal Decontamination Using Topical Nonabsorbable Antibiotics On The Incidence Of Nosocomial Respiratory Tract Infections In Multiple Trauma Patients," <i>J Trauma</i> , Vol 27, No. 4, pp. 357-364, 1987			
	D74	TABLAN, O. et al., "Guideline For Prevention Of Nosocomial Pneumonia," <i>Infection Control and Hospital Epidemiology</i> , Vol 15, No. 9, 587-627, September 1994			
	D75	TETTEROO, G. et al., "Selective Decontamination To Reduce Gram-Negative Colonisation And Infections After Oesophageal Resection," <i>Lancet</i> 1990;335:704-7.			
↪	D76	TETTEROO, G. et al., "Effects Of Selective Decontamination On Gram-Negative Colonisation, Infections And Development Of Bacterial Resistance In Esophageal Resection," <i>Intensive Care Med</i> 1990;16:S224-8.			

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✓	D77	TORRES, A. et al., "Gastric And Pharyngeal Flora In Nosocomial Pneumonia Acquired During Mechanical Ventilation," <i>Ame Rev Resp Dis</i> Vol. 148, pp. 352-357, 1993	
	D78	ULRICH, C. et al., "Selective Decontamination Of The Digestive Tract With Norfloxacin In The Prevention Of ICU-Acquired Infections: A Prospective Randomized Study," <i>Intensive Care Med</i> 1989;15:424-31.	
	D79	UNERTL, K. et al., "Prevention Of Colonization And Respiratory Infections In Long-Term Ventilated Patients By Local Antimicrobial Prophylaxis," <i>Intensive Care Med</i> 1987;13:106-13.	
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	D82	VERWAEST, C. et al., "Randomized, Controlled Trial Of Selective Digestive Decontamination In 600 Mechanically Ventilated Patients In A Multidisciplinary Intensive Care Unit," <i>Crit Care Med</i> 1997;25:63-71.	
	D83	WIENER, J. et al., "A Randomized, Double-Blind, Placebo-Controlled Trial Of Selective Digestive Decontamination In A Medical-Surgical Intensive Care Unit," <i>Clin Infect Dis</i> 1995;20:861-7.	
	D84	WINTER, R. et al., "A Controlled Trial Of Selective Decontamination Of The Digestive Tract In Intensive Care And Its Effect On Nosocomial Infection," <i>J Antimicrob Chemother</i> 1992;30:73-87.	
✓	D85	ZOBEL, G. et al., "Reduction Of Colonization And Infection Rate During Pediatric Intensive Care By Selective Decontamination Of The Digestive Tract," <i>Crit Care Med</i> 1991;19:12 12-6.	

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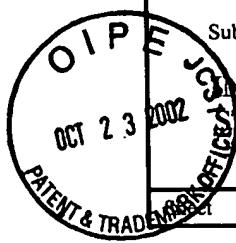
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<sup>1</sup> Unique citation designation number.

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<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

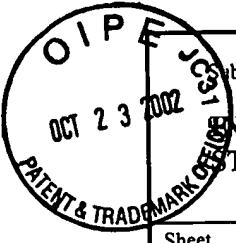
**For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.**

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

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Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)



<p style="text-align: center;">Substitute for form 1449B/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p>		<i>Complete if Known</i>	
		<b>Application Number</b>	10/075,924
		<b>Filing Date</b>	February 12, 2002
		<b>First Named Inventor</b>	Rebecca REDMAN
		<b>Group Art Unit</b>	1646
		<b>Examiner Name</b>	Not yet assigned.
Sheet	of	Attorney Docket Number	INBI-009/01US

#### **OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

Examiner Signature	Kr	Date Considered	12/11/03
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number.

<sup>2</sup> Applicant is to place a check mark here if English language Translation attached.